1488 '99 AUG -2 P1:18



JUL 3 0 1999

Food and Drug Administration Rockville MD 20857

Mr. Sas Weber 111055 Gee-Norman Rd. Belgrade, MT 59714

Dear Mr. Weber:

This is in response to your letter dated June 14, 1999, concerning the use of recombinant Bovine Growth Hormone (rBGH) in dairy cows.

Thank you for sharing your concerns on this issue. The use of drugs in livestock and poultry is strictly regulated. Before any drug intended for use in animals is approved, it must undergo extensive chemical and toxicological testing which must demonstrate that the food from these animals is safe for human consumption.

Bovine somatotropin (bST) was approved by the Food and Drug Administration (FDA) in 1993. The recombinant, or genetically engineered form of bST (rBST) is virtually identical to a cow's natural somatotropin, a hormone produced in its own pituitary gland that stimulates milk production. Since bST is a protein-based hormone, rbST is broken down during digestion, which makes it biologically inactive and incapable of having any effect in humans or animals. Over 120 studies were reviewed by FDA scientists that examined the safety of milk and meat from dairy cows treated with rbST. They concluded that there was no increased health risk to consumers.

I am enclosing materials which provide further information concerning this matter. In addition, I am forwarding your letter to Dockets Management Branch for inclusion in Docket Number 98P-1194 -- Withdrawal of NADA Approval for Posilac -- rBGH. Please visit our Internet Home Page at http://www.fda.gov/cvm.

Sincerely yours,

Karen A. Kandra

Consumer Safety Officer

Center for Veterinary Medicine

Laren a. Kandra

Enclosures

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CENTER FOR DRUG EVALUATION & RESEARCH EXECUTIVE SECRETARIAT STAFF CONTROL FORM

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From:

WEBER, SAS

Affiliation:

Address:

CorrType: letter

DUE DATE: 8/22/99

Rec'd Date: 7/22/99

Doc Date: 6/14/99

To: CDER

Subject:

URGING THE FDA TO

REMOVE BOVINE GROWTH HORMONE (RBGH) IN DAIRY

cows

Office	OfficeName	Action	Date Sent	Due Date	Returned
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FYI

Office	OfficeName
CVM	

Comments:

URGING FDA TO REMOVE BOVINE GROWTH HORMONE (RBGH) IN DAIRY COWS

DEAR SIRS WHO MAY BE CONCERNED -

I AM WRITING TO INFORM YOU OF MY DISAPPROVAL OF YOUR POLICY MUDWING THE USE OF recombinant Bonne GROWTH HORMONE (+ BGH) IN DAIRY cows.

CONSIDERING THE RISKS AND UNANSWERED QUESTIONS, THE NEGLIGIBUS GAIN, AND THE FACT THAT NO OTHER INDUSTRIANTED COUNTRY HAS APPROVED 173 USE, YOUR # POUCY IS UNCONSCIONABLE.

HOPE ENOUGH PORUL OUTERY WILL & HELP SWAMY YOU TO REVERSE YOUR POUCH

THANK YOU IN ADVANCE FOR USTENING.

Yours -

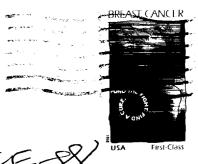
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